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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/084,491	05/27/98	MOORE	P PF378

022195
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HM12/1023

EXAMINER	
SLOBODYANSKY,E	
ART UNIT	PAPER NUMBER
1652	27

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/084,491	Applicant(s) Moore et al.
	Examiner Elizabeth Slobodyansky	Group Art Unit 1652

☒ Responsive to communication(s) filed on Aug 23, 2001 .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 76-182 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 76-182 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

The request filed on August 23, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/084,491 is acceptable and a CPA has been established. An action on the CPA follows.

The preliminary amendment filed August 23, 2001 amending the specification to correct clerical errors, canceling claims 21-55, 57-70, 73 and 74 and adding claims 76-182 has been entered.

Claims 76-182 are pending.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 76-182 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Claims 76-182 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 76-182 encompass DNA molecules encoding a polypeptide comprising SEQ ID NO:2, fragments thereof, structurally homologous polypeptides and fragments thereof.

The specification discloses a DNA of SEQ ID NO:1 encoding a protein of 263 amino acids (SEQ ID NO:2). The specification discloses that "SEQ ID NO:2 is about 21.3% identical" to human t-PA sequence shown at Figure 2 (page 9, lines 16-17). Figure 2 shows an alignment of residues 191-516 of human t-PA (residues 1-325 of SEQ ID NO:3) and SEQ ID NO:2. Therefore, the overall percent identity with t-PA is much lower. There is no additional data to support putative function. Such data would include a higher homology for the specific domains, such as protease domain, and location of putative catalytic triad in SEQ ID NO:2, for example. The sequence search performed by PTO shows that SEQ ID NO:2 and SEQ ID NO:3 have no appreciable homology. In fact, the specification does not provide any evidence of an enzymatic activity for the protein encoded by SEQ ID NO:1. Therefore, as disclosed, a protein of SEQ ID NO:2 is an uncharacterized protein. In view of this, the polynucleotide of SEQ ID NO:1 encoding the protein of SEQ ID NO:2 has no specific, substantial and well-established utility.

Furthermore, claims 166-182 recite a nucleic acid molecule comprising 30- and 50 nucleotide fragments of SEQ ID NO:1. A nucleic acid molecule of claims 166-182 is

not limited in length to said fragments. Therefore, claims 166-182 encompass countless number of sequences with an unknown function. There is no guidance presented as to what is the specific function of the sequences. There is no guidance as to which amino acid residues are important in the function of t-PALP and therefore, what are the residues that can be substituted, deleted or added without affecting the function. Since the instant specification does not disclose a credible "real world" use for a DNA comprising 30/50 nucleotides, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful. Due to the unpredictable nature of the art, the lack of guidance set forth by the specification regarding a specific function of a protein, and a great number of encompassed polypeptides, it would require further research to find the use for a peptide encoded by a nucleic acid molecule of claims 166-182.

Claims 76-182 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

-170,173-

Claims 166-182 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules comprising at least 30 or 50 nucleotides of SEQ ID NO:1.

The specification does not contain any disclosure of the function of all DNA sequences that comprise at least 30 or 50 nucleotides of SEQ ID NO:1. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 166-182 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fragment consisting of at least 30 or 50 nucleotides of SEQ ID NO:1, respectively, does not reasonably provide enablement for a fragment comprising at least 30 or 50 nucleotides of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 166-182 are drawn to a nucleic acid molecule comprising 30 or 50 nucleotide fragments of SEQ ID NO:1. An isolated polynucleotide of claims 166-182 is not limited in length. Further, there is no information regarding other nucleotides contained in a claimed polynucleotide comprising 30 or 50 of SEQ ID NO:1. Therefore, claims 166-182 encompass countless number of sequences with an unknown function.

There is no guidance presented as to what is the specific function of the sequences. It is unpredictable what is the function of an encoded polypeptide. Although it is routine in the art to make a nucleotide sequence, it is not routine and it is extremely unpredictable what the structure of a polypeptide encoded by said nucleotide sequence would be and how this polypeptide, once made, could function. Due to the unpredictable nature of the art, the lack of guidance set forth by the specification regarding a specific function of a polypeptide encoded by a polynucleotide that comprises 30 or 50 nucleotides of SEQ ID NO:1, and a great number of encompassed

polynucleotides, it would require undue experimentation for one skilled in the art to use a nucleic acid molecule of claims 166-182.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 88, 96, 104, 112, 114-123, 125, 133, 135-144, 146, 154, 157, 165, 174 and 182 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 88, 104, 125, 146, 157 and 174 recites the limitation "said heterologous polynucleotide". There is insufficient antecedent basis for this limitation in the claims.

Claims 96, 112, 133, 154, 165 and 182 are unclear because they are drawn to a method for producing a protein by culturing a host cell under conditions suitable to produce a polypeptide.

Claims 114-123 and 135-144 are dependent claims reciting a nucleic acid molecule which "further comprises a first polynucleotide" whereas "a first polynucleotide" is already recited in a respective independent claim (emphasis added).

It is unclear whether claims 114-123 and 135-144 are encompassing one "first polynucleotide" or two of the same.

Response to Arguments

Applicant's arguments filed August 23, 2001 have been fully considered but they are not persuasive.

Applicants argue that there is substantial homology between SEQ ID NO:2 and t-PA. They refer to several pages in the specification and to Figure 2 (page 23, 2nd paragraph). On page 9, lines 16-17, the specification discloses that "SEQ ID NO:2 is about 21.3% identical" to human t-PA sequence shown at Figure 2. Of note, Figure 2 shows an alignment of residues 191-516 of human t-PA (residues 1-325 of SEQ ID NO:3) and SEQ ID NO:2. Therefore, the overall percent identity with t-PA is much lower. There is no additional data to support the putative function. Such data would include a higher homology for the specific domains, such as protease domain, and location of putative catalytic triad in SEQ ID NO:2, for example. The sequence search performed by PTO shows that SEQ ID NO:2 and SEQ ID NO:3 have no appreciable homology. In fact, the specification does not provide any evidence of an enzymatic activity for the protein encoded by SEQ ID NO:1. Therefore, as disclosed, a protein of SEQ ID NO:2 is deemed to be an uncharacterized protein that needs further characterization. However, this further characterization is part of the act of invention

and until it has been undertaken, Applicant's claimed invention is incomplete. In view of this, the polynucleotide of SEQ ID NO:1 encoding the protein of SEQ ID NO:2 has no specific, substantial and well-established utility.

The instant claims are drawn to a DNA encoding a protein of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that the t-PALP of the instant application was, as of the filing date, useful for the same purposes as t-PA as stated by Applicants on page 23, last paragraph, of their Remarks. Until some actual and specific significance can be attributed to the protein identified in the specification as t-PALP, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date. Since the instant specification does not disclose a credible "real world" use for t-PALP, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

Applicants further argue that "their position coincides that of the Unites States Patent and Trademark Office" referring to Example 10 in the Utility Guidelines (page 25, 1st paragraph). Said example analyzes utility of a novel DNA ligase based on its

95% similarity to the known DNA ligases and find that it has well established utility. In the examiner's view, this example is different from the claimed invention because of the level of the sequence similarity as discussed above.

Regarding 112, 1st paragraph, rejections, Applicants argue that "an Applicants is not required to explicitly describe each of the trees in the forest" (page 27, 1st paragraph). The examiner agrees that there is no need to describe each and every "tree", just sufficient number of representatives. In this case this number is one. It consists of a fragment.

Conclusion

All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

October 19, 2001